12th Annual Clinical Trials Summit 2021

#VIct

"A critical guide for successfully conducting clinical trials"

20th May 2021, Virtual Conference (Time Zone - IST)

AGENDA AT A GLANCE

Key Speakers Include

K BANGARURAJAN
Adviser
CDSCO (New Delhi)

KAMAL K HALDER
ADCI
CDSCO (East Zone Kolkata)

OMPRAKASH S. SADHWANI
Former Joint Commissioner and Controlling Authority, FDA (Maharashtra state)

AMGAD SHEBL
Director, Global Clinical Safety & PV / Clinical R & D, CSL Behring (Germany)

RAVI SEKHAR KASIBHATTA
Senior Vice President, Clinical Research
Lupin

MIRCEA CIUCA
Global Therapeutic Area, Head - Global Clinical Safety and PV, CSL Behring (Switzerland)

ASHOK SRIVASTAVA
CEO & CMO, Trans Atlantic Therapeutics (USA), COVI-19 Vaccine and Drug Development

ARANI CHATTERJEE
Senior Vice President, Clinical Research
Aurobindo Pharma

ANIRBAN ROY CHOWDHURY
Vice President - Clinical Research & Pharmacovigilance, Bharat Serums and Vaccines

ARUN BHATT
Consultant – Clinical Research & Development

MILIND ANTANI
Leader, Pharma and Healthcare
Nishith Desai Associates

PANKAJ GUPTA
Chief Scientific Officer
Novartis

SEEMA PAI
Director - India Cluster, GSSO, Clinical Development & Operations, Global Product Development, Pfizer

MOHAN RAVURU
Director, Medical and Scientific Affairs, APAC
Abbott Rapid Diagnostics

AMMAR RAZA
Regional Medical Director - Middle East & Africa (MEA), Allergan Aesthetics, Abbvie (UAE)

RAJENDRA JANI
Senior Subject Expert & Advisor Clinical Research Consultant

GANESH DIVEKAR
Vice President - Clinical Operations and Biometrics, SIRO Clinpharm

TAUSIF AHMED
Director - Global Clinical Management
Dr. Reddy's Laboratories

RAJEEV SHRIVASTAVA
Associate Director - Regulatory Affairs and Pharmacovigilance, Eli Lilly

KRANTHI KIRAN PEBBILI
Director and Cluster Head - Medical Affairs
Dr. Reddy's Laboratories

RISHI JAIN
Medical Director
AbbVie

AMIT KUMAR
Head – Clinical Trials, Publications and Medical Excellence, AstraZeneca

Conceptualised By

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Key Speakers Include

DILIP PAWAR
Head - Medical Affairs and Pharmacovigilance
Unichem Laboratories

PRASHANT BODHE
Head Clinical Operations
Rubicon Research

MANISH MISHRA
Chief Executive Officer
Labaid Hospitals and Diagnostics

RENUKA NEOGI
CPL Manager
Sanofi

HARSHA K RAJASIMHA
Founder and CEO
Jeeva Informatics Solutions

KAVYA KADAM
Consultant Global Clinical Trials

VAIBHAV SALVI
Head – Medical Information, Asia
Sanofi

SNEHA GUPTA
Manager Regulatory Affairs
Sanofi

VISHWAS SOVANI
Founder Director
Pharmawisdom

KRUNAL KAVATHIYA
Medical Affairs
Torrent Pharmaceuticals

SILVER PARTNER

Jeeva INFORMATICS

EXHIBITOR

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CONFERENCE INTRODUCTION

According to a report, it's predicted that the global Contract Research Organization (CRO) market size was earlier estimated at US$ 34.5 billion in 2018 and is now projected to stretch US$ 55.3 billion by 2024, as we are looking at a growth of CAGR of 8.2% during 2019 to 2024. Indian clinical trials market size is predicted to reach US$ 3.15 billion by 2025. The global clinical trials market size is expected to reach USD 69.8 billion by 2027. It is estimated to register a CAGR of 8.7% over the forecast period which is a good sign for clinical trials.

12th Annual Clinical Trials Summit 2021 will provide a platform to discuss on the futuristic advancements in clinical trials and clinical research. This multidisciplinary program involves broad participation of people from clinical trials community from around the globe who are focused on learning more about clinical research, clinical trials planning and management.

This event opens discussion of timely topics of mutual theoretical and practical interest for clinical trial investigators who are developing new drugs and biologics. This groundbreaking platform continues the conversation between business, academics, patient advocacy, and regulatory agencies to discuss new methods and solutions to statistical challenges relevant to the design and analysis of clinical trials collaboratively in the real world. It is high time that we look into innovative strategies, new technologies, effective and quality collaborations to address these issues, which can cater to the needs of the patient and the industry.

This conference intends to focus on the global health and clinical trials around the world. Bioethics, regulations, patient recruitment, site selection, real-world data, data integration & Strategy, outsourcing, vendor management, quality (QbD) in Trial Conduct, risk-based monitoring, clinical auditing & financial planning and other significant topics that play a key role in clinical trials will be addressed along with innovative sessions on new technologies, effective and quality collaborations.

It gives us immense pleasure in welcoming you to the **12th Annual Clinical Trials Summit 2021**. I wish and pray that all our efforts will be beneficial to our industries and to our country at large

KEY THEMES DISCUSSED

- Clinical trials in India: Impact of COVID-19 and beyond
- The impact of COVID-19 on clinical trials
- Strategies implemented during tiring times of Covid-19 while conducting trials
- Medical management and adverse events
- Concerns, complexities & the way forward in performing clinical trials
- Addressing COVID-19's global effect on clinical trials and the way ahead
- Challenges with Info: How to preserve data consistency & integrity
- Data collection, integrity and security issues and how to resolve them to facilitate good trial results
- Improving patient - centricity by protecting patients, especially in pandemic.
- What are the current challenges faced while recruiting patients? & Solutions
- Tech perspective - The future of clinical science and the recognition of best practices to speed up progress
- What improvements in the industry are needed in order to properly accept emerging technologies?
- Strategic partnership and outsourcing approaches
- Different approaches to choosing the best CRO to ensure the fulfillment of your needs
- Understand the current framework of clinical trial regulations in India
- Update on the new Clinical Trial Regulation, timescale for applications, implementing acts
- Be part of a major networking opportunity

WHO SHOULD ATTEND AND WHO YOU'LL MEET

CEO's, CTO's, CIO's, Presidents, Vice Presidents, Directors Heads & Managers of:

Clinical Research & Development, Clinical Research Services, Clinical Operations, Clinical Data Management, Clinical IT, Clinical Trials, Medical Affairs, Regulatory Affairs, Compliance, Quality control / Assurance /GCP, Clinical Study Design, Safety Surveillance, Subject Recruitment, E-Clinical Systems

WHY SHOULD YOU ATTEND?

Get more from the event, with a **broader scope bringing the whole communications value chain together**. Enjoy and make the best out of our **dedicated networking time, meet the leading international vendors** showcasing the products of tomorrow in the co-located exhibition. **Expand your knowledge** of the latest business models and strategies in the high-level conference.

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DAY ONE - 20th May 2021

09:20 - Welcome Address & Virtual Conference Platform Instructions

MARKET OVERVIEW & ANALYSIS

09:30 – Impact of Covid-19 pandemic on conducting global clinical trials - Focus on safety aspects

- Protecting patients while keeping data integrity
- Some aspects of Regulatory guidance worldwide
- Adapting risk mitigation strategies
- Medical evaluation of adverse events
- Impact of vaccines

MIRCEA CIUCA
Global Therapeutic Area Head - Global Clinical Safety and Pharmacovigilance, CSL Behring (Switzerland)

10:00 – Diagnostic testing in the times of SARS-CoV-2 variants and COVID-19 vaccines

MOHAN RAVURU
Director, Medical and Scientific Affairs, APAC
Abbott Rapid Diagnostics

10:30 – Morning Coffee / Tea & Discussion

CHALLENGES & OPPORTUNITIES

10:50 – DISCUSSION WITH EXPERTS: Concerns, complexities & the way forward in performing clinical trials

- Addressing COVID-19's global effect on clinical trials and the way ahead
- How to enhance clinical research capabilities
- Challenges and opportunities for sponsors while conducting clinical trials during pandemic
- Will COVID-19 hold us back?
- With the declaration of COVID-19 as a global pandemic, how the Indian healthcare industry can deliver optimally with limited resources and many challenges
- How sponsors, researchers and clinical trial professionals respond to this situation and recognise and minimise possible threats and obstacles in order to execute clinical trials
- Real world evidence / Non interventional studies and its implications for healthcare improvement

Moderator:

DILIP PAWAR
Head - Medical Affairs and Pharmacovigilance
Unichem Laboratories

Panellists:

AMGAD SHEBL
Director, Global Clinical Safety & Pharmacovigilance / Clinical R & D, CSL Behring (Germany)

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VAIBHAV SALVI
Head – Medical Information, Asia
Sanofi

IMPACT OF TECHNOLOGY

11:40 – COVID-19 & Technological Transformation of Clinical Research - Why, What & How?

- Impact of COVID-19 on Clinical Research
- COVID-19 as a Catalyst for Digital Transformation
- Why and how digital transformation happened?
- Some examples of transformational technologies put to use
- How will CR look like in the future?

AMMAR RAZA
Regional Medical Director - Middle East & Africa (MEA) Allergan Aesthetics, Abbvie (UAE)

12:10 - Networking luncheon

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DAY ONE - 20th May 2021

Afternoon Chair Person

13:20 – DISCUSSION WITH EXPERTS: Improving patient - centricity by protecting patients, especially in pandemic

- What are the challenges faced while recruiting patients?
- Adopting the correct methodologies to help and drive patient-centered trials
- What are the risks of compromised data integrity and how to resolve this issue
- Key conditions for ensuring success in direct-to-patient trials
- Addressing patient-centric research in the time of COVID-19
- Addressing wearable technology that may help to reduce patient burden in several ways

Moderator:

PRASHANT BODHE
Head Clinical Operations
Rubicon Research

Panellists:

KAMAL K HALDER
ADCI
CDSCO (East Zone Kolkata)

ARUN BHATT
Consultant – Clinical Research & Development

SEEMA PAI
Director - India Cluster, GSSO, Clinical Development & Operations, Global Product Development, Pfizer

KRANTHI KIRAN PEBBILI
Director and Cluster Head - Medical Affairs
Dr. Reddy's Laboratories

RENUKA NEOGI
CPL Manager
Sanofi

REGULATORY

14:20 – DISCUSSION WITH EXPERTS: Current framework of clinical trial regulations in India

- Update on the new Clinical Trial Regulation, timescale for applications, implementing acts
- What key changes can be introduced?
- Roles and responsibilities: sponsor and investigators
- Settling in after the pandemic

Moderator:

MILIND ANTANI
Leader, Pharma and Healthcare
Nishith Desai Associates

Panellists:

K BANGARURAJAN
Adviser
CDSCO (New Delhi)

OMPRAKASH S. SADHWANI
Former Joint Commissioner and Controlling Authority
Food and Drug Administration (Maharashtra state)

RAJEEV SHRIVASTAVA
Associate Director - Regulatory Affairs and Pharmacovigilance, Eli Lilly

KRUNAL KAVATHIYA
Medical Affairs
Torrent Pharmaceuticals

SNEHA GUPTA
Manager Regulatory Affairs
Sanofi

KAVYA KADAM
Consultant Global Clinical Trials

15:10 – Afternoon Tea / Coffee

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DAY ONE - 20th May 2021

15:30 – DISCUSSION WITH EXPERTS: Strategic partnership and outsourcing approaches

- Different approaches to choosing the best CRO to ensure the fulfilment of your needs
- Establishing a team atmosphere for creative problem solving
- Constructing an effective model early on for a successful partnership with CROs
- Ensuring effective management and governance - appointing consistent sponsor and CRO responsibilities and obligations to avoid duplicative attempts and to set practical standards
- Addressing what the stakeholders need in order to continue delivering standards for a strategic partnership?
- Discussing what advantages would biopharmaceutical businesses gain from a strategic partnership?
- Clinical services and outsourcing

Moderator:

VISHWAS SOVANI
Founder Director
Pharmawisdom

Panellists:

RAVI SEKHAR KASIBHATTA
Senior Vice President
Lupin

ANIRBAN ROY CHOWDHURY
Vice President - Clinical Research & Pharmacovigilance
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Medical Director
AbbVie

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AstraZeneca

MANISH MISHRA
Chief Executive Officer
Labaid Hospitals and Diagnostics

16:20 – Orchestrating a Human-Centric Digital Experience to Accelerate Clinical Trial Operations from Anywhere

- Key findings from clinical trials stakeholder interviews before and during the pandemic
- Top priorities of clinical operations leaders
- Making sense of the perspectives of different stakeholders
- Striking the right Balance between technology innovation and human factors

HARSHA K RAJASIMHA
Founder and CEO
Jeeva Informatics Solutions

16:50 - Chairperson's closing remarks and end of conference

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AGENDA AT A GLANCE

REGISTER ONLINE :

Link : https://www.townscript.com/e/12th-annual-clinical-trials-summit-2021-virtual-conference-114022

For Multiple Bookings - Photocopy this form and send it to **bookings@virtueinsight.com**

REGISTRATION FORM

RESERVATION PRICING:

Standard Price

Cost per delegate

Fee: INR 8,000 + GST(18%)

Discounted Rate for Bulk Booking of More Than 5 Delegates

Please email us at **bookings@virtueinsight.com**

Registration Form Details:

Forename .....Surname .....

Job Title .....

Company .....

GST No (If Applicable) .....

Official Contact Number .....

Address .....

.....

Country .....Postcode.....

Phone .....Fax .....

Email .....

I confirm that I have read & agree to the terms and conditions of booking..... (Please Tick) ☐

Signature .....

Methods of Payments:

By Cheque - Complete and return the above registration form via post or email, together with your cheque payable to Virtue Insight.

By Bank Transfer:

Account Name	- Virtue Insight
Account Type	- Current
Account Number	- 915020031763553
Bank Name	- Axis Bank
Bank Address	- 2/8 LAMBERT NAGAR, 1st cross street, Virugambakkam, Chennai - 600 092
Branch Name	- Virugambakkam, Chennai
Swift Code	- AXISINBB211
NEFT / IFSC Code	- UTIB0000211
Micro Code	- 600211010

CERTIFICATION

E-Certificate of attendance would be provided to attendees on request, upon completion of conference

Queries:

Should you have any questions on bookings,
Please feel free to contact us.

Email: info@virtueinsight.com
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TERMS AND CONDITIONS:

Payment terms: Virtue Insight requires the full amount to be paid before the conference. We may refuse entry to delegates who have not paid their invoice in full.

Cancellations: Delegates and vendors are subject to the following charges and refunds upon withdrawal or cancellation between 2-3 month's prior 75% cancellation fee/ 25% refund. Less than 2 months prior to the event Full cancellation fee / No refund.

Administration Fee: If you cancel your participation (once confirmed) and haven't paid the attendance fee you will be liable to pay an administration fee of INR 5,000

Substitutions/Name Change: If you are unable to attend you may nominate, in writing, another delegate to take your place at any time prior to the start of the event. This can be done at no extra cost.

Indemnity: Virtue Insight reserves the right to make alterations to the conference/executive briefing content, timing, speakers or venue without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of Virtue Insight. If such a situation arises, we will reschedule the event.

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